

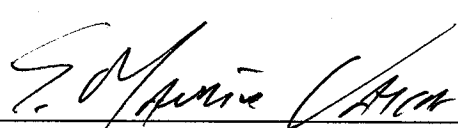
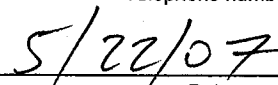
Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)

Approved for use through xx/xx/200x. OMB 0651-00xx

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)	
		CRDS-0062 (CRD0931CIP)	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on _____ Signature _____ Typed or printed name _____	Application Number	Filed	
	10/829,074	April 21, 2004	
	First Named Inventor	Robert Falotico	
	Art Unit	Examiner	
	1615	Sharon E. Kennedy	
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.			
This request is being filed with a notice of appeal.			
The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.			
I am the			
<input type="checkbox"/> applicant/inventor.		Signature	
<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)		S. Maurice Valla	
		Typed or printed name	
<input checked="" type="checkbox"/> attorney or agent of record.	43,966	215-564-8392	
Registration number		Telephone number	
<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34.			
Registration number if acting under 37 CFR 1.34		Date	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.			
<input type="checkbox"/> *Total of _____ forms are submitted.			

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

DOCKET NO.: CRDS-0062 (CRD0931CIP)
Application No.: 10/829,074
Office Action Dated: February 22, 2007

**PATENT
REPLY FILED UNDER EXPEDITED
PROCEDURE PURSUANT TO
37 CFR § 1.116**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Robert Falotico, et al.

Confirmation No.: **5950**

Application No.: **10/829,074**

Group Art Unit: **1615**

Filing Date: **April 21, 2004**

Examiner: **Sharon E. Kennedy**

For: **Drug/Drug Delivery Systems for the Prevention and Treatment of Vascular Disease**

**ELECTRONICALLY FILED
DATE OF DEPOSIT: May 22, 2007**

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REMARKS TO SUPPORT PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicants respectfully request review of the above-captioned application prior to filing of an appeal brief. Claims 15 to 36 are pending, and stand rejected under 35 U.S.C. §§ 112, second paragraph, and 103(a). A Notice of Appeal is filed herewith.

The Subject Invention

The pending claims are directed to drug delivery devices and methods of using same to inhibit neointimal proliferation in a human coronary artery resulting from percutaneous transluminal coronary angioplasty.

As recited in independent claim 15, the device comprises: an intraluminal stent; a biocompatible, nonerodible polymeric coating affixed to the stent; and rapamycin or a macrocyclic triene analog thereof that is incorporated into the polymeric coating. The claim further recites that the device provides an in-stent late loss in diameter at 12 months following implantation in a human of less than about 0.5 mm, as measured by quantitative coronary angiography.

Independent claim 19 recites that device provides a *mean* in-stent late loss in diameter in a *human population* at 12 months following implantation of less than about 0.5 mm, as measured by quantitative coronary angiography.

The various dependent claims further specify additional characteristics of the device, such as that the device provides an in-stent diameter stenosis at 12 months following implantation in a human of less than about 22%, as measured by quantitative coronary angiography (claims 17 and 21), the amount of drug incorporated into the coating (claims 31, 32, 34 and 35), or that the device release a portion of the dose of rapamycin or a macrocyclic triene analog thereof at about six weeks following intraluminal implantation (claims 33 and 36).

The Claims Comply with 35 U.S.C. § 112, Second Paragraph

The Examiner relies on text posted on the Boston Scientific website that is said to teach that “[i]n-stent late loss . . . does not provide any useful information as to the efficiency of a stent delivery device” (Office Action dated November 6, 2006, at 5, last paragraph; Office Action dated February 22, 2006, at 6, third paragraph).

It is clear that the Office Action misinterprets and overstates the relevance of this web posting. The cited text does not state that in-stent late loss “holds no real value,” as asserted by the Examiner (Office Action dated November 6, 2006 at 6, first paragraph), but that “late loss is an interesting measure” (cited document, at page 3). Although Boston Scientific posits that analysis of in-segment late loss provides more complete information than analysis of in-stent late loss, it does not assert that the latter measure is meaningless.¹

In fact, the cited text merely presents a hypothetical (and since refuted) argument as to why in-segment late loss (as measured in terms of risk of either target lesion revascularization (TLR) or angiographic binary restenosis (BAR)) might be a better predictor of efficacy than in-stent late loss. Applicants have previously submitted three peer-reviewed articles, published in a widely respected scientific journal, that clearly refute the Examiner’s assertion that in-stent late loss is meaningless. As these articles make clear, the ability of a given stent to provide an in-stent late loss of less than 0.5 mm, and more preferably less than 0.3 mm (as

¹ The cited text is not a peer-reviewed scientific article, but appears to be a mere advertisement whose purpose is to show alleged superiority for Boston Scientific’s TAXUS® stent over another brand of stent.

recited in several of the dependent claims) is a strong indicator of that stent's ability to inhibit neointimal proliferation.

In any event, the extent to which late loss serves as a predictor of efficacy is of no moment in assessing whether the instant claims are definite. The test for compliance with the Section 112, second paragraph, is whether one skilled in the art would understand the metes and bounds of the claim when read in light of the specification. *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692 (Fed. Cir. 2001) (citing *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986)). As the Court of Appeals for the Federal Circuit has stated, a claim is indefinite "if its legal scope is not clear enough that a person of ordinary skill in the art could determine whether a particular [product or method] infringes or not." *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F. 3d 1373, 1384 (Fed. Cir. 2003).

The instant claims clearly satisfy this standard. They recite, *inter alia*, that the device provide an in-stent late loss in diameter at 12 months following implantation in a human of less than about 0.5 mm, as measured by quantitative coronary angiography. It is unrefuted that methods for performing quantitative coronary angiography are well established and readily practiced by those in the art. The point in time at which in-stent late loss is to be determined is also specified in the claim, leaving no ambiguity as to how and when one would determine whether or not a particular stent meets the limitations of the claims.

Moreover, it is clear that those of skilled in the art routinely measure properties such as late loss, and utilize this property to characterize the efficacy of their stent products. For example, an article published in EuroIntervention in 2005 (already of record in this case as Exhibit 8 of the Declaration by Attorney to Support Petition to Make Special) reports on the one-year results of the Spirit First trial of durable polymer everolimus-eluting stents, and cites to both the in-stent late loss and diameter stenosis at 12 months post implantation as evidence of the stents' safety and efficacy. Thus, the Examiner's assertion that the inclusion of this limitation "places a potential infringer in an untenable position since the data holds no real value" (Office Action dated February 22, 2007, at 6, third paragraph) is simply wrong.

Applicants respectfully submit that the scope of the claims is clearly defined, and that those skilled in the art could readily determine whether a particular device or method

infringes the claims. Accordingly, Applicants respectfully request that the Examiner's rejection of pending claims 15 to 36 under 35 U.S.C. 112, second paragraph, be withdrawn.

Prima Facie Obviousness Has Not Been Established

The pending claims also stand rejected under 35 U.S.C. § 103(a) over Mitchell, et al., U.S. Patent No. 5,288,711 ("the Mitchell Patent") in view of Kamath et al., U.S. Patent No. 6,335,029 ("the Kamath Patent"). This rejection is improper because the Examiner's proposed combination of the patent's respective teachings would not produce the claimed invention.

The Examiner relies upon the Mitchell Patent "to exemplify that the use of rapamycin in stents to prevent smooth muscle cell hyperplasia after balloon angioplasty has been well known for some time" (Office Action dated February 22, 2007, at 9, paragraph 2). The Examiner recognizes, however, that the Mitchell patent does not disclose the use of polymeric coatings, but rather "merely stat[es] . . . that a 'vascular stent can be impregnated with . . . rapamycin'" (*Id.*). The Examiner relies upon the Kamath Patent to make up for this deficiency, based on the patent's teaching that antiproliferative drugs (other than rapamycin or its analogs) can be incorporated in polymeric coatings on stents (*Id.*).

As even the Examiner recognizes, however, neither the Mitchell Patent nor the Kamath Patent contains any teaching or suggestion that any device disclosed therein provides an in-stent late loss in diameter at 12 months following implantation in a human of less than about 0.5 mm, as measured by quantitative coronary angiography. Thus, as a matter of law, the patents fail to establish that the claimed inventions would have been obvious *In re Royka*, 490 F. 2d 981, 985 (CCPA 1974)); *see also*, MPEP § 2143.03 (to establish obviousness of a claimed invention, all of the limitations set forth in the claims must be taught or suggested by the prior art).²

Obviousness-type Double Patenting Rejections

The Office Actions of record also contain several rejections for nonstatutory, obviousness-type double patenting over several co-owned patents and pending applications.

² The Examiner improperly attempts to ignore the claim element relating to in-stent late loss by relying on the previously stated arguments regarding alleged indefiniteness of this claim element (Office Action dated February 22, 2007, p. 9, paragraph 3). Not only is this not permitted under current PTO procedures (*see* MPEP § 2143.03), but (as noted above) in-stent late loss is not indefinite and thus must be given due consideration as an element of the claims

DOCKET NO.: CRDS-0062 (CRD0931CIP)
Application No.: 10/829,074
Office Action Dated: February 22, 2007

**PATENT
REPLY FILED UNDER EXPEDITED
PROCEDURE PURSUANT TO
37 CFR § 1.116**

Each of these rejections rely, at least in part, on the Examiner's assertions regarding alleged indefiniteness of the present claims, and the Examiner's refusal to grant the claim recitation of specific in-stent late loss parameters any patentable weight. Applicants have requested that these rejections be held in abeyance until this issue is resolved. However, Applicants note that none of the claims in the patents and applications cited by the Examiner contain this claim limitation. Applicants respectfully submit that when this claim element is properly recognized as a definite element of the device recited in the claims, it is evident that the double patenting rejections of record are improper.

In the interest of full disclosure, Applicants note that this claim element is being introduced into the claims of another copending application (U.S. Application Serial No. 10/852,517) that has not been cited by the Examiner. Applicants plan to file a terminal disclaimer over that application upon a determination that the instant claims are allowable.

CONCLUSION

In view of the foregoing, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §§ 112, second paragraph and 103(a).

Date: May 22, 2007

/S. Maurice Valla/
S. Maurice Valla
Registration No. 43,966

Woodcock Washburn LLP
Cira Centre
2929 Arch Street, 12th Floor
Philadelphia, PA 19104-2891
Telephone: (215) 568-3100
Facsimile: (215) 568-3439